

October 18, 2021

Interview (10/11/21) Supplement, Bryan Pesta


Dear Committee,

Thank you for allowing me to supplement my answers from last Monday's interview.

1. IRB Approval. All three datasets I applied for (TCP, ABCD, and ADD Health) were from dbGaP. The first was TCP, wherein the application clearly stated that IRB approval was not needed:

Authorized Access

- **Data access provided by:** [dbGaP Authorized Access](#)
- **Release Date:** May 17, 2018
- **Embargo Release Date:** May 17, 2018
- [Data Use Certification Requirements \(DUC\)](#)
- **Public Posting of Genomic Summary Results:** Allowed
- **Use Restrictions**

Consent group	Is IRB required?	Data Access Committee	Number of participants
General Research Use (NPU) 	No	Joint Addiction, Aging, and Mental Health DAC (JAAMH-DAC@list.nih.gov)	9496

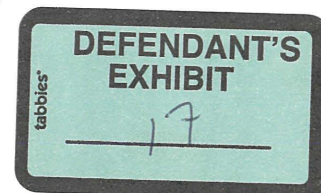
- [List of components](#) downloadable from [Authorized Access](#)

So, I didn't seek IRB approval, across three separate TCP applications, when applying for use of the TCP data. I did, however, apply for IRB approval on the Add Health dataset, because the website there indicated that it was required.

However, I hope to amend my answer to the committee's question: "Would deviating from the NIH's DAR then require CSU/IRB approval?" Upon further reflection, my answer is "no."

Suppose that CSU/IRB approved the deviations, but that the NIH did not. The NIH would certainly not give me the data. Conversely, suppose the NIH approved the data, but CSU/IRB did not. This would be odd. I would most likely file an appeal, in that if the NIH was ok with giving me their own restricted access archived data, how could CSU/IRB reject the proposal? Thus, CSU/IRB approval seems irrelevant to my applications for NIH/TCP data. The former offers no layer of (ethics) protection beyond what NIH approval already offers.

A timing issue also exists regarding IRB approval and me uploading data to the external website. I did not realize the external server was an issue until September of 2019, when the NIH initially complained to me. This, however, was after the Lasker et al. paper was published. It would therefore not make sense to retroactively apply for CSU/IRB approval for a paper that was already published. I think if I would have done this post facto, it would be another allegation against me. At any rate, my argument is that CSU/IRB approval provides no additional "ethics protection" beyond what the TCP application already offers. As such, CSU/IRB was not required, and I suspect this is also why TCP listed that "[CSU] IRB is not required."



Finally, I still don't understand the issue, which was brought up more than once, regarding me analyzing data either by combining ethnicities or by analyzing them separately. If the committee still deems this issue important, could they please clarify?

2. HPDF. A committee member mentioned that they had never heard of a faculty member creating a 501(c)(3) to fund his/her research. Here's my speculation for this: The topic of race differences in intelligence is so polarizing that at least some private citizens are willing to donate their own money to fund the research. So, we created a 501(c)(3) to capitalize on this demand. In contrast, I also do research on bibliometrics, and well-being differences across the 50 U.S. states. No one will give me money for researching these topics. I suspect this is true for probably all other research topics pursued by CSU faculty. That is, despite the importance of the topics, private citizens aren't lining up to donate money for the causes, because the research topics are relatively uncontroversial.

This could explain why committee members have never heard of creating a non-profit to fund a research program. I had never heard of it either before creating one. I suspect this is likely unprecedented at CSU, and so no policy probably exists for or against it here.

At any rate, I did concede that some (a relatively small percent) of the funds I received were used to pursue dbGaP research. Examples of where I spent the money here included a computer, meals, and Uber rides to and from my house. However, I'm left wondering, "so what?" The funds were used for legitimate business reasons given our non-profit's mission; no one was harmed, and we are now under the watchful eyes (e.g., IRS) that result from having a 501(c)(3) which is experiencing revenue. If, on the other hand, the issue here is revenue sharing with CSU, please let me know how that should be done.

3. External Server. Would the committee be willing to stipulate (or argue otherwise) that data uploaded to the external server, <https://hirisplex.erasmusmc.nl/>, cannot be used to identify participants? My take is still that the NIH would never have approved the other article's (<https://www.nature.com/articles/s42003-020-01461-8/figures/3>) use of the external site, were it remotely possible to identify research participants.

Note, also, that Bird et al. use "weasel words" in their allegation against me here: "the authors...imputed genotype information that could further contribute to the identifiability of study samples." What does "could further contribute" mean? Either researchers can identify participants from the uploaded files, or they cannot. They cannot.